70064



31 March 2000

CERTIFIED MAIL



Robert Moore, Ph.D.
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street, SW
Washington, D.C. 20204

Re: Food Labeling; Notification of Statements on Dietary Supplement.

Dear Dr. Moore:

Pursuant to 21 C.F.R. Subpart F, section 101.93, Chattem, Incorporated ("Chattem", the distributor, located at 1715 West 38th Street, Chattanooga, TN 37409) wishes to notify the Food and Drug Administration that it has, within the past 30 days, commenced marketing a dietary supplement that bears statements of nutritional support in its labeling.

The following statements are being made for the dietary supplement Propalmex®, which contains zinc, standardized saw palmetto berry extract, standardized pumpkin seed oil extract, and lycopene as nutritional ingredients.

- Supports prostate health.
- In clinical trials, a daily dose of 320 mg. of scientifically standardized saw palmetto extract helped to support prostate health.

CHATTEM, INC. 1715 West 38th Street Chattanooga, TN 37409 (423) 821-2037

975 - 0162

Dr. Moore Page 2 03 March 2000

- Scientific evidence, including epidemiological research and a recent clinical study using lycopene from Lyc-O-MatoTM standardized tomato extract, supports lycopene's benefits to prostate health. Lyc-O-MatoTM lycopene is a powerful antioxidant, acting to neutralize oxygen free radical molecules which can damage cells.
- An essential mineral in human nutrition, zinc plays an important role in maintaining prostate health.

These statements are accompanied by disclaimer, which is prominently displayed in a box in bold-faced type. The information contained in this notice is complete and accurate. Chattern maintains on file substantiation that these statements are truthful and non-misleading. An original and two copies of this notification are being submitted.

Sincerely,

Michael Law, Ph.D.

Manager, Regulatory Affairs

ML Enclosure